

REMARKS

Reconsideration of the present application, as amended, is respectfully requested.

A. STATUS OF THE CLAIMS

As a result of the present amendment, claims 1 and 3-23 are presented in the case for continued prosecution. Claim 2 has been cancelled without prejudice. Claim 1 has been amended to include the subject matter in original claim 2. Claim 3 has been amended to depend from claim 1. New claim 9 has been added to more particularly set forth that which the applicants consider to be their invention. Support for new claim 9 is found, for example, at page 6, line 22 through page 7, line 1 of the specification. New claims 10-23 have also been added to more particularly set forth that which the applicants consider to be their invention. Support for new claims 10-23 is found, for example, at page 7, line 3 through page 8, line 2; page 14, lines 19-21; and Examples 2-6. No new matter has been added.

B. REQUIREMENT FOR INFORMATION

The Examiner required under 37 CFR 1.105 the applicants to provide various information about the art described in the specification. The Examiner indicated that the requested information is necessary because *Acanthopanax* (ogalpi) is well-known and widely used in Korea for various ailments and the Examiner has very limited resources for obtaining Korean non-patent literature documents on the subject of *Acanthopanax*.

In response, the applicants provide a copy of the publications mentioned in the specification, and a concise explanation of the publications.

Burnett AL, J Urol, 1997, 157, 320-4 (Exhibit 1):

The publication is mentioned at page 8, line 6 of the specification. NO (nitric oxide) is involved in the relaxation of corpus cavernosus smooth muscle. The publication merely educates the reader about the physiological relationship between NO and penile erection.

Burnett AL et al., Science, 1992, 257, 401-3 (Exhibit 2):

The publication is mentioned at page 8, lines 6-7 of the specification. NO (nitric oxide) is involved in the penile erection of rats *in vivo*. The publication merely educates the reader about the physiological relationship between NO and penile erection.

Gonzalez-Cadavid NF, Ignarro LJ, Rajfer J, *Mol Urol*, 1999, 3, 51-9 (Exhibit 3):

A copy of the abstract is provided because the entire document is not readily obtained.

The publication is mentioned at page 8, lines 15-17 of the specification. The publication merely educates the reader about the physiological relationship between NO, cGMP and penile erection.

Christ GJ et al., *Br J Pharmacol*, 1990, 101, 375-81 (Exhibit 4):

The publication is mentioned at page 9, line 17 of the specification. Penile erection is mediated by an alpha-adrenergic receptor. The publication merely educates the reader about the physiological relationship between an alpha-adrenergic receptor and penile erection.

Fovaeus M et al., *J Urol*, 1987, 138, 1267-72 (Exhibit 5):

The publication is mentioned at page 10, lines 3-4 of the specification. Calcium movement via Ca channel blockade is involved in the erectile dysfunction. The publication merely educates the reader about the physiological relationship between calcium movements and penile erection.

Karaki H et al., *Pharmacol Rev*, 1997, 49, 157-230 (Exhibit 6):

The publication is mentioned at page 10, lines 4-5 of the specification. The publication includes a review of calcium movements in smooth muscle. The publication merely educates the reader about the physiological relationship between calcium movements and penile erection.

Kim N et al., *J Clin Invest*, 1991, 88, 112-118 (Exhibit 7)

The publication is mentioned at page 20, lines 18-19 of the specification. The page referred to as "238-42" of the publication is an typographical error. The specification has been corrected to include the correct page information of the publication "112-118", accordingly. Endothelial cells in corpus cavernous smooth muscle are involved in the penile erection. The method of removing endothelial cells described in the specification corresponds to that of the publication.

In addition, the applicants provide a copy of the publications pertinent to the descriptions

found on page 4 of the specification and a concise explanation of the publications.

The Pharmacology of Chinese Herbs, Kee Chang Huang; CRC press,
1993, pages 46-48. (Exhibit 8):

The publication shows that the species *Acanthopanax senticosus* is known to effect on male sexual function. See page 48 of the publication. The claims, as amended herein, are limited to the alcohol extracts of different species selected from a group consisting of *A. divaricatus* var. *albeofructus* and *A. koreanum* distinguishable over *A. senticosus*. It is requested that the Examiner independently consider the entire document including the description referred to herein to determine any disclosure pertinent to the claimed invention, if any. This publication is disclosed in the Information Disclosure Statement submitted herewith.

Chinese Drugs of Plant Origin, W Tang and G Eisenbrand, Springer-Verlag,
1992 (Exhibit 9):

The publication discloses that a water extract of *A. senticosus* protected mice from stress-induced decreases in sex behavior. See the first paragraph under the section entitled "1.3 Pharmacology" on page 9. The claims, as amended herein, are limited to the alcohol extracts of difference species, *A. divaricatus* var. *albeofructus* and *A. koreanum*. It is requested that the Examiner independently consider the entire document, including the description referred to herein, to determine any disclosure pertinent to the claimed invention, if any. This publication is disclosed in the Information Disclosure Statement submitted herewith.

It is respectfully urged that this submission of the publications does not represent an admission that each or all of them are "prior art" references within the meaning of the statutory and case law. The applicants reserve the right to contend, where appropriate, that a reference asserted against any claim of the present application is not prior art under the facts and the law.

The applicants also reserve the right to present appropriate arguments and/or evidence to establish patentability over the references, should one or more of the references be applied against the claims of the present application.

It is also respectfully requested that the applicants reserve the right to provide alternative positions and mechanisms if necessary.

In addition, some of botanical and morphological aspects distinguishable among from different Acanthopanax species are provided.

Acanthopanax is a genus in the family of araliaceae which includes about 60 genera and 600 species. There are more than 20 species in Acanthopanax genus, 1 species from Russia, 7~8 species from China, 3 species from Japan and 8 species from Korea. *A. senticosus* is significantly distinguishable over other Acanthopanax (ogalpi) species in many aspects of botanical and morphological features. *A. senticosus* has light green leaves whose both surfaces have many twigs and whose stems have fine splinters on the surfaces. On the other hand, other Acanthopanax genus has dark green leaves and the surfaces of their stems have none or a few thick splinters, if any. The flowers of *A. senticosus* are divided into 5 parts. *A. senticosus* is known to grow in hilly areas of Korea, Hokkaido of Japan, the Heilong Jiang of China and Siberia of Russia.

A. koreanum has splinters whose fundus is wide and has a triangle-shape. The flowers of *A. koreanum* are divided into 2 parts. It grows in the southern area of Korean peninsula, particularly in Jeju island, thus named as *A. koreanum*.

C. THE CLAIMS ARE NOVEL UNDER 35 U.S.C. §102(b)

The Office Action indicated that “Claims 13 and 4-8 are rejected under 35 USC 102(b) as being anticipated by Endo (US Patent No. 5,378,466)”. The Examiner indicated that “Claim 3 appears to be free of the art” and is rejected because it is dependent from a rejected base claim. It is respectfully requested that the Examiner clarifies rejected claims.

The applicants note the Examiner’s finding that the claimed alcohol extract of *Acanthopanax divaricatus* var. *albofructus* is free of the prior art. See the second paragraph of the Office Action on page 2.

Referring to column 2 of Endo, the Examiner indicated that Endo discloses a therapeutic agent containing an ethanolic extraction of *Acanthopanax senticosus* Harms for treatment of allergic diseases. The Examiner indicated that the claimed extract is the same extract as the prior art, obtained from the same parts (leaves, stems, root) referring to the description at column 1 of Endo.

The applicants respectfully disagree. The Examiner's attention is directed to the requirement that a rejection under 35 U.S.C. 102(b) teach all of the elements of the rejected claims within the cited reference.

The claimed invention, as amended herein, is directed to alcohol extracts of A. divaricatus var, albeofructus and A. koreanum for improving erectile dysfunction, thus rendering the rejection moot.

On the other hand, Endo et al. discloses the extract of A. senticosus for the treatment of allergic diseases. As such, Endo does not teach the claimed alcohol extracts nor anticipate the subject matter of claim1 and its dependent claims.

The oral administration of the claimed alcohol extract of A. divaricatus var. albeofructus allowed the increase in cGMP and cAMP in corpus cavernous smooth muscle of rats and the treatment of the penile erection in human. See Example 5 on page and Example 6 on pages 39-40 of the specification. It is urged that efficacies of one species is unpredictable from that of other species.

For all of the above reasons, reconsideration and withdrawal of the rejections is respectfully requested.

D. FEES

This response is being filed with a Petition for a one-month extension of time and proper fee therefor via credit card authorization. March 29, 2008 was a Saturday. Therefore, this response is still considered timely. No further fee is believed to be due. If it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

E. CONCLUSION

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
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